Form	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Psychotropic Medication Informed Consent (Form MMH–1)	300	2	1.50	900
Psychotropic Medication Assent Notice (Form MMH–2)	300	1	0.75	225

Estimated Total Annual Burden Hours: 1,125.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; 45 CFR 410; Flores v. Reno Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996); *Lucas R. et al.* v. *Becerra et al.* (Case No. 2:18–CV–05741 DMG PLA) Psychotropic Medication Settlement Agreement.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–16043 Filed 7–19–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2442]

Recommendations for Investigational and Licensed COVID–19 Convalescent Plasma; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for immediate implementation entitled ''Recommendations for Investigational and Licensed COVID–19 Convalescent Plasma; Guidance for Industry.'' The purpose of this guidance is to provide FDA's recommendations to blood establishments for the submission of a Biologics License Application (BLA) for the manufacture of COVID–19 convalescent plasma intended for transfusion in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The guidance also provides FDA's recommendations for investigational new drug applications (INDs) for investigational COVID–19 convalescent plasma for transfusion.

DATES: The announcement of the guidance is published in the **Federal Register** on July 22, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–2442 for ''Recommendations for Licensed COVID–19 Convalescent Plasma; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive labels to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for blood establishments entitled ''Recommendations for Investigational and Licensed COVID–19 Convalescent Plasma; Guidance for Industry.'' We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C))). We made this determination because the revisions to the guidance reflect the current epidemiology of COVID–19 and provide updated recommendations needed by blood establishments and sponsors. Specifically, we are issuing this guidance to ensure that blood establishments and sponsors are aware of our current recommendations to expedite the timely development of COVID–19 convalescent plasma. Immediate implementation of the guidance is required to facilitate the licensure of COVID–19 convalescent plasma to protect the public health. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's GGP regulation (§ 10.115(g)(3)(D)).

COVID–19 convalescent plasma is plasma containing antibodies to SARS–CoV–2 intended for transfusion that is collected from individuals who have recovered from COVID–19. FDA first issued an emergency use authorization (EUA) on August 23, 2020, for COVID–19 convalescent plasma for the treatment of hospitalized patients with COVID–19, pursuant to section 564 of the FD&C Act (21 U.S.C. 360bbb–3). FDA has subsequently reissued the EUA with revisions. Most recently, on December 28, 2021, FDA revised the EUA to limit authorization to the use of COVID–19 convalescent plasma with high titers of anti-SARS–CoV–2 antibodies for the treatment of COVID–19 in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The purpose of this guidance is to provide FDA's recommendations on two regulatory pathways for the manufacture of COVID–19 convalescent plasma. Specifically, the guidance provides recommendations to blood establishments for the submission of a BLA for the manufacture of COVID–19 convalescent plasma for transfusion intended to treat patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The guidance also provides FDA's recommendations for INDs for investigational COVID–19 convalescent plasma for transfusion.

The guidance represents the current thinking of FDA on investigational and licensed COVID–19 convalescent plasma. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

FDA has also issued a separate guidance entitled ''Investigational COVID–19 Convalescent Plasma,'' which was most recently updated in October 2023 (88 FR 15417). The ''Investigational COVID–19 Convalescent Plasma'' guidance provides recommendations and additional information related to the EUA for COVID–19 convalescent plasma, as well as recommendations for administering COVID–19 convalescent plasma under the IND pathway in accordance with 21 CFR part 312. The recommendations in section III.A.2 of the guidance being announced today pertaining to investigational new drug applications for COVID–19 convalescent plasma supersede the recommendations in section III.C. of the ''Investigational COVID–19 Convalescent Plasma'' guidance. We intend to revise the ''Investigational COVID–19 Convalescent Plasma'' guidance to reflect this change.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 606 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR part 630 have been approved under OMB control number 0910–0795.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16046 Filed 7–19–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1298]

Agency Information Collection Activities; Proposed Collection; Comment Request; Diversity Action Plans for Clinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each